

SPECIFICATION

Oxytetracycline Dihydrate (EP8.0)

Aspect	Yellow, crystalline powder.
Formula	$C_{22}H_{24}N_2O_9 \cdot 2H_2O$

Properties	
Identification	A.: Thin-layer chromatogram meets the requirements B.: Positive C.: Positive
pH	4.5 – 7.5
Specific optical rotation	-203° – -216°
Absorbance (353nm)	290-310
Light-absorbing impurities	430nm: NMT 0.25 490nm: NMT 0.20
Related substances	Impurity A: 4-epioxytetracycline NMT 0.5 %
	Impurity B: Tetracycline NMT 2.0 %
	Impurity C: Other substances NMT 2.0 %
Heavy metals	NMT 50ppm
Water	6.0 – 9.0 %
Sulfated ash	NMT 0.5 %
Bacterial endotoxins	Less than 0.4 IU/mg (internal)
Assay(HPLC)	95.0-102.0%(anhydrous)
Solubility	Very slightly soluble in water.It dissolves in dilute acid and alkaline solutions.
Expiry Date	Four years after production date
Storage	In an airtight container, protected from light.

Transport information	See our latest safety data sheet
Safety data sheet	Yes
Classified as hazardous as per EU regulation	See our latest safety data sheet